Butler, Jennie C

From: Sent:

To: Cc:

Subject:

Daniel Sotak [Daniel.Sotak@tdh.state.tx.us]
Friday, July 09, 1999 5:20 PM
fdadockets@oc.fda.gov
STENNYSON@bfds.tdh.state.tx.us; CCULMO@bfds.tdh.state.tx.us;
RROGERS@bfds.tdh.state.tx.us; TBRINCK@bfds.tdh.state.tx.us
Comments: Sunlamp Products Performance Standards

Dear Sirs,

Thank you very much for accepting our comments.

Daniel Sotak Tanning Program Manager Division of Drugs and Medical Devices Texas Department of Health

98N-1170

ر 21



Texas Department of Health

William R. Archer III, M.D. Commissioner

http://www.tdh.state.tx.us

Patti J. Patterson, M.D., M.P.H. Executive Deputy Commissioner

1100 West 49th Street Austin, Texas 78756-3199 512/458-7111

July 9, 1999

Docket No. 98N-1170

Medical Devices; Sunlamp Products Performance Standard; Request for Comments and Information; Extension of Comment Period

We are being impacted by many of the same issues you have outlined in your proposed amendments. We have exhausted considerable resources surrounding sun lamp equivalency issues. Some manner of standardization of these products would be welcome relief.

State dermatologists recently drafted the following three recommendations to be used as guidelines for any proposed legislation or rule changes concerning tanning. We forward them for your consideration.

1. Use of the "Fitzpatrick Scale"—scale for classifying skin type, based on the skin's Reaction to the first 10 to 45 minutes of sun exposure after the winter season:

Skin type	Sunburning and tanning history
<u>1</u>	Always burns easily; never tans
<u>2</u>	Always burns easily; tans minimally
<u>3</u>	Burns moderately; tans gradually
<u>4</u>	Burns minimally; always tans well
<u>5</u>	Rarely burns; tans profusely
<u>6</u>	Never burns; deeply pigmented

2. An operator shall post three color photographs on or near each warning sign. The first photograph must show the magnified lesions of a person with basal cell carcinoma. The second photograph must show the magnified lesions of a person with squamous cell carcinoma. The third photo must show the magnified lesions of a person with malignant melanoma.

. 3. Adamantly support the prohibition of tanning of minors.

Since these issues cross numerous boundaries, we feel that this is an excellent opportunity for state and federal agencies to interact and work cooperatively on an issue of national importance. We welcome the opportunity to assist in such an endeavor, and thank you for accepting these comments.

Cynthia T. Culmo, R.Ph Director Drugs and Medical Devices Division (512) 719-0237 fax: (512) 719-0261

internet: cynthia.culmo@tdh.state.tx.us